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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,124	10/10/2003	Fred H. Burbank	R0367-01002	2747

7590 12/16/2005

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EXAMINER	
JEFFERY, JOHN A	
ART UNIT	**PAPER NUMBER**
3742	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/684,124	**Applicant(s)** BURBANK ET AL.	
	Examiner John A. Jeffery	**Art Unit** 3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 35-55* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1 and 35-55* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *10 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
  Paper No(s)/Mail Date *8/12/05,11/14/05*.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter (US 4,863,470) or Sinaiko (US 3,341,417), Fulton, III et al. (US 6,270,464), and further in view of Voegele et al. (US 6,220,248). Carter discloses an X-ray detectable body 16 embedded in gelatin body 14. See Figs. 1 and 2 and col. 2, lines 32-33, col. 2, lines 47-48 and lines 59-63. Also, Sinaiko discloses an X-ray detectable body embedded in a gelatin body. See (1) col. 2, lines 30-37 and 59-62, (2) col. 3, lines 53-65, and (3) col. 3, line 74 - col. 4, line 28.

The claim differs from the previously cited prior art in calling for the gelatin to be dehydrated and configured for delivery to a biopsy site through a delivery cannula. But forming biopsy site markers from dehydrated materials, including gelatins, is well known in the art. Fulton, III et al. (US 6,270,464), for example, forms a biopsy site marker 34 from a dehydrated collagen so that the marker swells and softens in its post-delivery state following delivery from delivery device 32. See (1) col. 5, lines 3-21, (2) col. 6, lines 47-50, and (3) Fig. 5. The marker is ultrasonically detectable. Col. 3, lines 58-59. Furthermore, Fulton, III et al. (US 6,270,464) notes in col. 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material. In view of Fulton, III et al. (US 6,270,464), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a dehydrated gelatin in the previously-described X-ray detectable bodies so that that the body swells and softens in its post-delivery state. Such a feature conserves space during storage in view of the marker's smaller size prior to implantation and subsequent swelling. Regarding the limitation in the preamble that the marker is "storable," the markers of the prior art are inherently storable.

The claim also differs from the previously cited prior art in calling for a plurality of separate ultrasonically-detectable bodies. Delivering a plurality of detectable bodies via a cannula, however, is well known in the art. Voegele et al. (US 6,220,248), for example, discloses in Fig. 19 a cannula that is adapted to eject a plurality of biopsy markers 76 to a desired biopsy site via an ejector rod. See col. 9, lines 3-9. Such an arrangement enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites. In view of Voegele et al. (US 6,220,248), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Claims 35-43, 50-52, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (US 6,270,464) in view of Yamamoto (US 4,847,049) and further in view of Voegele et al. (US 6,220,248). Fulton, III et al. (US 6,270,464) discloses a biopsy site marker 34 from a dehydrated collagen so that the marker swells and softens in its post-delivery state following delivery from delivery device 32. See (1) col. 5, lines 3-21, (2) col. 6, lines 47-50, and (3) Fig. 5. In addition to its visual detectability via a coloring agent (col. 3, lines 53-54), the marker is also ultrasonically and radiographically detectable. Col. 3, lines 56-59. Furthermore, Fulton, III et al. (US 6,270,464) notes in col. 6, lines 57-63 that a gelatin (line 63) may be substituted for the collagen material.

The claims differ from Fulton, III et al. (US 6,270,464) in calling for a radiographically detectable metallic ion bound to the bioabsorbable material. But binding metallic ions to collagens in medical devices used in contact with bodily fluids and tissues is well known in the art to protect against bacterial and fungal attack. Yamamoto (US 4,847,049), for example, discloses contacting a renatured, cross-linked collagen with silver ion-containing solution with a pH from 4.0–9.0 to cause silver ions to be chelated to functional groups in the renatured collagen. The silver-chelated collagen is then exposed to UV radiation at a 210-310 nm wavelength for 5-15 minutes (col. 4, lines 23-24) to strengthen the binding of the silver ions to the renatured collagen. See col. 2, lines 7-19 and 60-68. In view of Yamamoto (US 4,847,049), it would have been obvious to one of ordinary skill in the art at the time of the invention to bind a radiographically detectable metallic ion to the bioabsorbable material of Fulton, III et al.

(US 6,270,464) to cause silver ions to be chelated to functional groups in the collagen, thus further protecting against bacterial and fungal attack.

The claims also differ from the previously cited prior art in calling for a plurality of separate ultrasonically-detectable bodies. Delivering a plurality of detectable bodies via a cannula, however, is well known in the art. Voegele et al. (US 6,220,248), for example, discloses in Fig. 19 a cannula that is adapted to eject a plurality of biopsy markers 76 to a desired biopsy site via an ejector rod. See col. 9, lines 3-9. Such an arrangement enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites. In view of Voegele et al. (US 6,220,248), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Regarding claims 35 and 50, the cited prior art does not expressly disclose the body's ability to remain solid at 40° C. However, not only is such a feature implied by the prior art to ensure the marker remained intact after implantation (i.e., upon exposure to body temperature), the skilled artisan would know to select such a body because the marker is intended to be implanted into the patient and therefore must remain solid at temperatures several degrees above body temperature. Therefore, it would have been obvious to one of ordinary skill in the art to provide a body that is solid at 40° C in the previously described apparatus to ensure the marker remained intact after implantation.

Claims 44, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (US 6,270,464) in view of Voegele et al. (US 6,220,248). The claims differ from the previously cited prior art in calling for a delivery cannula with inner lumen and plunger to press against the marker bodies to discharge them from the cannula's discharge port. But delivery cannulas with such features are well known in the art. Voegele et al. (US 6,220,248), for example, discloses in Figs. 6, 7, 9, 11, and 21-25 a delivery cannula for implanting biopsy site markers that ejects biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. Such a feature eliminates a procedural step thus saving time. See col. 5, lines 38-50. Moreover, as noted in col. 9, lines 3-10, the device can eject multiple markers individually in series. In view of Voegele et al. (US 6,220,248), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a marker delivery cannula and plunger in lieu of the marker delivery device of Fulton, III et al. (US 6,270,464) to eject biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window, thus eliminating a procedural step and saving time.

The claims also differ from Fulton, III et al. in calling for a plurality of separate ultrasonically-detectable bodies. Delivering a plurality of detectable bodies via a cannula, however, is well known in the art. Voegele et al. (US 6,220,248), for example, discloses in Fig. 19 a cannula that is adapted to eject a plurality of biopsy markers 76 to a desired biopsy site via an ejector rod. See col. 9, lines 3-9. Such an arrangement enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites. In view of Voegele et al. (US 6,220,248), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Claims 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton, III et al. (US 6,270,464) in view of Yamamoto (US 4,847,049) and further in view of Voegele et al. (US 6,220,248). The claims differ from the previously cited prior art in calling for a delivery cannula with inner lumen and plunger to press against the marker bodies to discharge them from the cannula's discharge port. But delivery cannulas with such features are well known in the art. Voegele et al. (US 6,220,248), for example, discloses in Figs. 6, 7, 9, 11, and 21-25 a delivery cannula for implanting biopsy site markers that ejects biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window. Such a feature eliminates a procedural step thus saving time. See col. 5, lines 38-50. Moreover, as noted in col. 9, lines 3-10, the device can eject multiple markers individually in series. In view of Voegele et al. (US 6,220,248), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a marker delivery cannula and plunger in lieu of the marker delivery device of Fulton, III et al. (US 6,270,464) to eject biopsy markers from the cannula into the desired tissue without the need to push the distal end of the cannula out from the lateral biopsy window, thus eliminating a procedural step and saving time.

The claims differ from the previously cited prior art in calling for a plurality of separate ultrasonically-detectable bodies. Delivering a plurality of detectable bodies via a cannula, however, is well known in the art. Voegele et al. (US 6,220,248), for example, discloses in Fig. 19 a cannula that is adapted to eject a plurality of biopsy markers 76 to a desired biopsy site via an ejector rod. See col. 9, lines 3-9. Such an arrangement enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites. In view of Voegele et al. (US 6,220,248), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

Regarding claims 46-49, although the cited prior art does not disclose the specific Bloom rating of the body, the body of the cited prior art is nonetheless within the claimed Bloom rating range to achieve implantation (i.e., the body must possess the requisite degree of softness, but also a certain amount of firmness to facilitate implantation).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-38 and 44-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-65 of copending Application No. 10/719,448. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader in scope than the claims of the '448 application. *See In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Moreover, there is no apparent reason why applicant could not have presented the instant claims during prosecution of the '448 application.

Claims 39-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-65 of copending Application No. 10/719,448 in view of Yamamoto (US 4,847,049) and further in view of Voegele et al. (US 6,220,248). The claims differ from the claims of the '448 application in calling for a radiographically detectable metallic ion bound to the bioabsorbable material. But binding metallic ions to collagens in medical devices used in contact with bodily fluids and tissues is well known in the art to protect against bacterial and fungal attack. Yamamoto (US 4,847,049), for example, discloses contacting a renatured, cross-linked collagen with silver ion-containing solution with a pH from 4.0–9.0 to cause silver ions to be chelated to functional groups in the renatured collagen. The silver-chelated collagen is then exposed to UV radiation at a 210-310 nm wavelength for 5-15 minutes (col. 4, lines 23-24) to strengthen the binding of the silver ions to the renatured collagen. See col. 2, lines 7-19 and 60-68. In view of Yamamoto (US 4,847,049), it would have been obvious to one of ordinary skill in the art at the time of the invention to bind a radiographically detectable metallic ion to the bioabsorbable material of the '448 application to cause silver ions to be chelated to functional groups in the collagen, thus further protecting against bacterial and fungal attack.

The claims also differ from the claims of the '448 application in calling for a plurality of separate ultrasonically-detectable bodies. Delivering a plurality of detectable bodies via a cannula, however, is well known in the art. Voegele et al. (US 6,220,248), for example, discloses in Fig. 19 a cannula that is adapted to eject a plurality of biopsy markers 76 to a desired biopsy site via an ejector rod. See col. 9, lines 3-9. Such an arrangement enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites. In view of Voegele et al. (US 6,220,248), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a multiple detectable bodies in lieu of a single body in the previously described apparatus to enables implanting an array of markers with a single cannula, thus enabling implantation at multiple biopsy sites.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments have been considered but are deemed to be moot in view of the new grounds of rejection.

Regarding the double patenting rejection, applicant argues that the obviousness-type double patenting rejection was based on claims 1 and 23 of the copending 10/719,448 application. Remarks filed 8/22/05, at 8. The examiner, however, did not base the double patenting rejection on those claims, but rather claims 31-65. See Non-final Office Action mailed 7/21/05, at 9. Thus, applicant's argument does not match the examiner's position. For the reasons set forth above, the double patenting rejections are proper.

Final Rejection

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Jeffery whose telephone number is (571) 272-4781. The examiner can normally be reached on Monday - Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans, can be reached on (571) 272-4777. All faxes should be sent to the centralized fax number at (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John a. Jeffery

JOHN A. JEFFERY
PRIMARY EXAMINER

12/11/05